

70051-112

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

3/28/2014

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MAR 28 2014

Susan Gallager, Regulatory Affairs Associate  
Certis USA.  
9145 Guilford Road, Suite 175  
Columbia MD 21046

RE: Product Name: CYD-X PLUS  
EPA Reg. No: 70051-112  
PC Code: 129090  
Decision No: D487360  
Submission No: 946605

Application for: Notification per PR Notice 98-10 – to add referral statement,  
alternate contents, update OMRI logo  
Application Date: January 23, 2014

Dear Ms. Gallager:

The Biopesticides and Pollution Prevention Division has received your application for Notification (per PR Notice 98-10) to add a referral statement, alternate contents, and update OMRI logo per the new seal to the above product. We have determined that this action falls within the scope of this Notice and our records have been duly noted; an updated stamped label reflecting the following changes will be placed in the registration jacket and uploaded to the Agency's Pesticide Product Label System.

A stamped copy of the label is enclosed for your records. If you have any questions regarding this letter, please contact Shanaz Bacchus of my staff (bacchus.shanaz@epa.gov; 703-308-8097).

Sincerely,

Kimberly Nesci, Chief  
Microbial Pesticides Branch  
Biopesticides and Pollution Prevention Division

Enclosure:

SB:7511P:032714:70051-112

CONCURRENCES

SYMBOL	7511P	7511P	7511P				
SURNAME	Bacchus	Bacchus	Nesci				
DATE	3/27/14	3/27/14	3/28/14				

OFFICIAL FILE COPY

Lab... audit



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**SUBLABEL A: Agricultural Use**  
(Additional Brand Name CYD-X® HP)

# CYD-X® PLUS

High Potency Aqueous Suspension  
Biological Insecticide for Control of the Codling Moth

 **FOR ORGANIC PRODUCTION**



<b>Active Ingredient*:</b> .....	
<i>Cydia pomonella</i> granulovirus.....	.06%
<b>Other Ingredients:</b> .....	99.94%
<b>Total</b> .....	100.00%..

\*Contains at least 3 x 10<sup>13</sup> viral occlusion bodies (OBs) per Liter.

**KEEP OUT OF REACH OF CHILDREN  
CAUTION**

**Net Contents: 6 fluid ounces, 1 Quart**

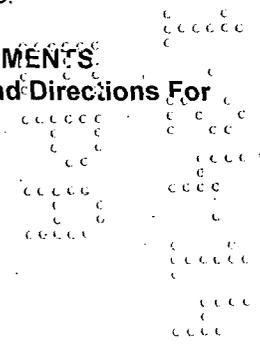
Lot No.:  
EPA Reg. No. 70051-112  
EPA Est. No. 70051-CA-001

Manufactured by  
Certis USA  
9145 Guilford Road  
Suite 175  
Columbia, MD 21046



CYD-X® PLUS is an insecticidal virus product for control of larvae of the codling moth. Read this label carefully. Refer to the Technical Bulletin for Additional Guidelines for Use.

**SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS.**  
**See inside panels for First Aid, Additional Precautionary Statements, and Directions For Use and Warranty Statement**



**PRECAUTIONARY STATEMENTS**

**HAZARDS TO HUMANS (AND DOMESTIC ANIMALS): CAUTION:**

Harmful if inhaled. Avoid breathing spray mist. Harmful if absorbed through skin. Avoid contact with skin, eyes or clothing. Causes moderate eye irritation. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

**FIRST AID**

**If inhaled:** Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth, if possible.

**If on skin or clothing:** Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes.

**If in eyes:** Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.

Call a poison control center or doctor for treatment advice.

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. Hot Line Number: 1-800-255-3924

**PERSONAL PROTECTIVE EQUIPMENT:**

Applicators and other handlers must wear:

- Long sleeved shirt and long pants
- Shoes plus socks

Protective eyewear such as goggles, face shield, or shielded safety glasses.

Mixers/loaders and applicators must wear a dust/mist filtering respirator meeting NIOSH standards of at least N-95, R-95, or P-95. Repeated exposure to high concentrations of microbial proteins can cause allergic sensitization.

Follow manufacturer's instructions for cleaning and maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

**Engineering Control Statements:**

When handlers use closed systems, enclosed cabs, or aircraft in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [40 CFR 170.240(d)(4-6)], the handler PPE requirements may be reduced or modified as specified in the WPS.

**IMPORTANT:** When reduced PPE is worn because a closed system is being used, handlers must be provided all PPE specified above for "applicators and other handlers" and have such PPE immediately available for use in an emergency, such as a spill or equipment break-down.

**USER SAFETY RECOMMENDATION**

**Users Should:**

Remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.

Remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

**ENVIRONMENTAL HAZARDS:**

Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment washwaters or rinsate.

**DIRECTIONS FOR USE**

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. For any requirements specific to your State or Tribe, consult the State or Tribal agency responsible for pesticide regulation.

Do not apply this product through any type of irrigation.

**AGRICULTURAL USE REQUIREMENTS**

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR part 170. This Standard contains requirements for the protection of agricultural workers on farms, forests, nurseries and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE) and restricted entry interval (REI). The requirements in this box only apply to uses of this product that are covered by the Worker Protection Standard.

Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 4 hours.

PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water is:

- Coveralls
- Waterproof gloves
- Shoes plus socks

**GENERAL INFORMATION**

**CYD-X® PLUS BIOLOGICAL INSECTICIDE**

**PRODUCT DESCRIPTION**

CYD-X® PLUS contains an insecticidal baculovirus (scientific name: *Cydia pomonella* granulovirus or CpGV) that is specific to larvae of the codling moth (*Cydia pomonella*). Because of this specificity to the codling moth, CYD-X® PLUS provides a unique opportunity for biological control of codling moth without harmful effects on humans, domestic animals, wildlife, beneficial insects and plants.

**BIOLOGICAL PROPERTIES and MODE OF ACTION**

CYD-X® PLUS is a biological insecticide which must be ingested by larvae in order to be effective. Upon ingestion, the viral occlusion bodies (OBs) dissolve in the larval midgut and release infectious virions. These enter the cells lining the digestive tract and replicate in the nuclei of those cells. The resulting progeny virus infects other tissues within the larva, which stops feeding and eventually dies from massive viral infection. After death, the larva disintegrates, releasing billions of new OBs which may infect other codling moth larvae upon ingestion. Death occurs 3 to 7 days after ingestion of CYD-X® PLUS, depending on dosage and ambient temperature. Death may occur more quickly at higher temperatures and higher dosage.

Baculoviruses have been found only in invertebrates; currently there are no reports of members of this family infecting vertebrates or plants. CYD-X® PLUS virions do not reproduce in mammalian cells.



## STORAGE AND DISPOSAL

### PESTICIDE STORAGE:

Store this product in original sealed container in a cool, dry place inaccessible to children and pets. Store at temperatures below 86°F. Bioactivity may be impaired by storage above 86°F. Storing the product in a freezer or refrigerator will extend its shelf life.

### PESTICIDE DISPOSAL:

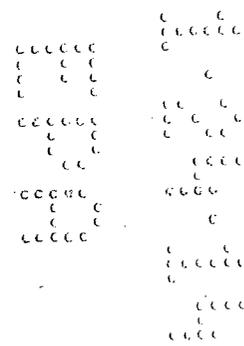
To avoid wastes, use all material in this container by application according to label directions. If wastes cannot be avoided, offer remaining product to a waste disposal facility or pesticide disposal program (often such programs are run by state or local governments or by industry).

### CONTAINER HANDLING:

Nonrefillable container. Do not reuse or refill this container. Offer for recycling, if appropriate. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain 10 seconds after the flow begins to drip. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. Then offer for recycling if available or puncture and dispose of in a sanitary landfill, or by incineration. Do not burn, unless allowed by State and local ordinances.

## WARRANTY

Certis USA L.L.C. warrants that the material contained herein conforms to the description on the label and is reasonably fit for the purposes referred to in the directions for use. Timing and method of application, weather, watering practices, nature of soil, the insect problem, condition of the crop, incompatibility with other chemicals not specifically recommended and other influencing factors in the use of this product are beyond the control of the seller. Buyer assumes all risks of use, storage or handling of this material not in strict accordance with directions given herein. NO OTHER EXPRESS OR IMPLIED WARRANTY OF THE FITNESS OR MERCHANTABILITY IS MADE.



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## Sublabel B: Homeowner Use

# CYD-X®PLUS

(Additional Brand Name CYD-X®HP)  
A High Potency Aqueous Suspension  
Biological Insecticide for Control of the Codling Moth  
In Home Garden settings

 FOR ORGANIC GARDENING



**Active Ingredient\*:**

*Cydia pomonella granulovirus*..... 0.06%

**Other Ingredients:**..... 99.94%

**Total**..... 100.00%

\*Contains at least 3 x 10<sup>13</sup> viral occlusion bodies (OBs) per Liter.

**KEEP OUT OF REACH OF CHILDREN  
CAUTION**

**Net Contents: 1.5 fl. oz. and 2.0 fl. oz.**

Lot No.:

EPA Reg. No. 70051-112

EPA Est. No. 70051-CA-001

Manufactured by:

Certis USA

9145 Guilford Road

Suite 175

Columbia, MD 21046

# CERTIS

CYD-X®PLUS is an insecticidal virus product for control of larvae of the codling moth. Read this label carefully. Refer to the Technical Bulletin for Additional Guidelines for Use.

**SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS**

**See inside panels for First Aid, Additional Precautionary Statements, and Directions For Use and Warranty Statement**

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## PRECAUTIONARY STATEMENTS

### HAZARDS TO HUMANS (AND DOMESTIC ANIMALS): CAUTION:

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## FIRST AID

**If inhaled:** Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth, if possible.

**If on skin or clothing:** Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes.

**If in eyes:** Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.

Call a poison control center or doctor for treatment advice.

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. Hot Line Number: 1-800-255-3924

## ENVIRONMENTAL HAZARDS:

To protect the environment, do not allow pesticide to enter or run off into storm drains, drainage ditches, gutters or surface waters. Applying this product in calm weather when rain is not predicted for the next 24 hours will help to ensure that wind or rain does not blow or wash pesticide off the treatment area. Rinsing application equipment over the treated area will help avoid run off to water bodies or drainage systems.

## DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. For any requirements specific to your State or Tribe, consult the State or Tribal agency responsible for pesticide regulation.

Do not apply this product through any type of irrigation.

## GENERAL INFORMATION

### CYD-X® PLUS BIOLOGICAL INSECTICIDE

#### PRODUCT DESCRIPTION

CYD-X® PLUS contains an insecticidal baculovirus (scientific name: *Cydia pomonella granulovirus*) that is specific to larvae of the codling moth (*Cydia pomonella*). Because of this specificity to the codling moth, CYD-X® PLUS provides a unique opportunity for biological control of codling moth without harmful effects on humans, domestic animals, wildlife, beneficial insects and plants.

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## **BIOLOGICAL PROPERTIES and MODE OF ACTION**

CYD-X® PLUS is a biological insecticide, which must be ingested by larvae in order to be effective. Upon ingestion, the viral occlusion bodies (OBs) dissolve in the larval midgut and release infectious virions. These enter the cells lining the digestive tract and replicate in the nuclei of those cells. The resulting progeny virus infect other tissues within the larva, which stops feeding and eventually dies from massive viral infection. After death, the larva disintegrates, releasing billions of new OBs, which may infect other codling moth larvae upon ingestion. Death occurs 3 to 7 days after ingestion of CYD-X® PLUS, depending on dosage and ambient temperature. Death may occur more quickly at higher temperatures and higher dosage.

Baculoviruses have been found only in invertebrates; currently, there are no reports of members of this family infecting vertebrates or plants. CYD-X® PLUS virions do not reproduce in mammalian cells. This product can be inactivated by continuous exposure to temperatures above 86°F. For best results, keep the product refrigerated or frozen when not in use.

## **MIXING INSTRUCTIONS**

**CYD-X® PLUS must be mixed with water and applied as a spray to fruit (apple, pear, plum, and walnut) and foliage. Use water at a pH near 7.0 in the spray-tank mix.**

### ***Application rate:***

Mix 1/2 teaspoon of CYD-X® PLUS per 5 gallons of water and apply directly to each tree using a hand pump sprayer or other suitable spray equipment. Spray just enough to wet all leaves and fruit with minimal run-off or dripping. Total coverage depends on the size of trees to be sprayed and the type of sprayer used.

### ***When to spray:***

Apply CYD-X® PLUS first in late spring or early summer, when eggs of the first generation of codling moth begin to hatch. For maximum effectiveness, apply CYD-X® PLUS at least twice during each larval generation. When pest pressure persists, additional applications of CYD-X® PLUS may be necessary in mid- to late summer. Consult your local Cooperative Extension Service for more information about the best timing of codling moth sprays.

CYD-X® PLUS breaks down under direct exposure to sunlight. If codling moths are still flying and laying eggs, reapply after 7 to 8 sunny days.

CYD-X® PLUS can be applied up to and including the day of harvest and storage.

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### **STORAGE AND DISPOSAL**

Do not contaminate water, food, or feed by storage and disposal.

#### **PESTICIDE STORAGE:**

Keep in original container. Store away from direct sunlight, feed, or foodstuffs. Keep container tightly sealed when not in use.

#### **PESTICIDE DISPOSAL AND CONTAINER HANDLING:**

Non-refillable container. Do not reuse or refill container.

#### **If empty:**

Place in trash or offer for recycling, if available.

#### **If partly filled:**

Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

### **WARRANTY**

Certis USA L.L.C. warrants that the material contained herein conforms to the description on the label and is reasonably fit for the purposes referred to in the directions for use. Timing and method of application, weather, watering practices, nature of soil, the insect problem, condition of the crop, incompatibility with other chemicals not specifically recommended and other influencing factors in the use of this product are beyond the control of the seller. Buyer assumes all risks of use, storage or handling of this material not in strict accordance with directions given herein. **NO OTHER EXPRESS OR IMPLIED WARRANTY OF THE FITNESS OR MERCHANTABILITY IS MADE.**